

EXHIBIT A

Scientific Committee on Emerging and Newly Identified Health Risks

SCENIHR

Preliminary opinion on: -

The safety of surgical meshes used in urogynaecological surgery

http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_27_en.htm

**Comments Submitted
By the IUGA**

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The European Commission through the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has produced a preliminary opinion on “The safety of surgical meshes used in urogynaecological surgery”. This was opened for public consultation on the 8th June 2015.

IUGA thought it was appropriate to prepare an official response and commissioned three members of the team that contributed to the 2nd IUGA Grafts roundtable published in 2012. The IUGA Board, ahead of submission on the 19th July 2013, reviewed the response.

Below is a summary of the comments submitted.

As an organization the reviewers were surprised that the period of consultation was so short for such an important topic. They were also disappointed that the European Commission had not approached a specialist society like IUGA to contribute to the selection of the external experts. They made a recommendation that the consultation period should be extended so that more practitioners could have the opportunity to respond and to include the results of the PROSPECT study which has been submitted for publication.

There was also a feeling that the committee had failed to do an appropriate literature search and had not described their search strategy adequately.

The reviewers were surprised that the committee had not made any recommendations for the methods of introduction of new devices or operations. They suggested that SCENIHR consider the recommendations of the 2nd IUGA Grafts round table, and use it as a template. The failure to suggest minimum standards is an oversight. Specifically it was felt that there should be an insistence on the use of animal studies before any mesh products were implanted in humans.

It was felt that it was inappropriate to rely too highly on the Amid classification which no longer covers all the available grafts and invalid to recommend Type I polypropylene above all others for vaginal repair. There was even more concern about recommending polyester mesh as it was felt there were both basic science and clinical reasons why this was not a suitable material for use in surgery, irrespective of the route of surgery. It was felt that this report failed to consider new materials such as polyvinylidene fluoride (PVDF) or hybrid materials such as poliglecaprone or titanium covered mesh. This further highlights the need to propose or endorse a strategy for the introduction of new materials and operations.

A number of scientific inaccuracies were highlighted in the report and corrections offered. For example the report had failed to distinguish between a sacrocolpopexy and a sacrohysteropexy which the reviewers felt were fundamentally different operations. They

suggested additional references for areas they did not think were well covered in the body of the report.

The reviewers endorsed SCENIHR's recommendations that there should be more effort made to do a risk assessment of patients ahead of the placement of mesh in an attempt to avoid implantation in those more likely to develop complications.

The reviewers also agreed with the recommendation that the consenting process needs to be more robust.

The SCENHIR report stated that there are considerable benefits for the use of mesh in certain individuals but that in some instances the benefits are uncertain. The reviewers felt that it was possibly beyond the scope of this report to make any recommendations on specific operations and that the report should concentrate more on the materials.